

food products, but caution must be exercised concerning poorly buffered foods. No more than 20 milliliters of distilled water should be added to each 100 grams of product. Determine the pH by immersing electrodes in the prepared paste after adjusting the temperature to 25 °C.

(iii) *Semisolid products.* Food products of a semisolid consistency, such as puddings, potato salad, etc., may be blended to a paste consistency, and the pH may be determined on the prepared paste. If more fluidity is required, 10 to 20 milliliters of distilled water may be added to 100 grams of product. Adjust the temperature of the prepared paste to 25 °C and determine its pH.

(iv) *Special product mixtures.* For special product mixtures such as anti-pasto, pour off the oil, blend the remaining product to a paste, and determine the pH of the blended paste. If more fluidity is required, add 10 to 20 milliliters of distilled water to each 100 grams of product and blend. Adjust the temperature of the prepared paste to 25 °C and determine its pH.

(7) *Process pH determination.* Obtain sample portions of material for pH determination.

(i) For process liquids, adjust the temperature of the liquid to 25 °C and determine the pH by immersing the electrodes in the liquid.

(ii) Drain solid materials on a sieve and blend to a workable paste. Adjust the temperature of the prepared paste to 25 °C and determine its pH.

(iii) If enough solid materials are available to make a paste, blend representative aliquots of liquid and solid materials to a workable paste. Adjust the temperature of the prepared paste to 25 °C and determine the equilibrated pH. Alternatively, blend the entire contents of the container to a uniform paste, adjust the temperature of the paste to 25 °C, and determine the equilibrated pH.

(b) *Colorimetric methods for the determination of pH.* This method may be used in lieu of the potentiometric method if the pH is 4.0 or lower.

(1) *Principle.* The colorimetric method for pH involves the use of indicator dyes in solutions that gradually change color over limited pH ranges. An indicator that has the greatest color

change at approximately the pH of the sample being tested is selected. The pH is determined by the color of the indicator when exposed to the sample under test.

(2) *Indicator solutions.* Most indicator solutions are prepared as a 0.04 percent solution of the indicator dye in alcohol. In testing, a few drops of indicator solution are added to 10-milliliter portions of the sample solution. Colors should be compared using a bright background. Approximate determinations can be made on white porcelain spot plates, the test colors being compared thereon with a set of color standards. More accurate colorimetric tests can be made using a comparator block fitted with sets of tubes of standard indicator solutions of known pH.

(3) *Indicator paper.* A paper tape treated with indicator dye is dipped into the sample solution. Depending upon the pH of the solution, the tape will change color and an approximate pH can be determined by comparison with a standard color chart.

(c) *Titrateable acidity.* Acceptable methods for determining titrateable acidity are described in the AOAC, 13th Ed. (1980), section 22.060, under “Titrateable Acidity—Official Final Action,” for “Indicator Method,” and section 22.061 for “Glass Electrode Method—Official Final Action,” which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(4)(ii) of this section. The procedure for preparing and standardizing the sodium hydroxide solution is described in the AOAC, 13th Ed. (1980), sections 50.032–50.035, under “Sodium Hydroxide—Official Final Action” by the “Standard Potassium Hydroxide Phthalate Method,” which is also incorporated by reference and available as set forth in paragraph (a)(4)(ii) of this section.

[44 FR 16235, Mar. 16, 1979, as amended at 47 FR 11822, Mar. 19, 1982; 49 FR 5609, Feb. 14, 1984; 54 FR 24892, June 12, 1989; 63 FR 14035, Mar. 24, 1998]

Subpart F—Records and Reports

§ 114.100 Records.

(a) Records shall be maintained of examinations of raw materials, packaging materials, and finished products,

and of suppliers' guarantees or certifications that verify compliance with Food and Drug Administration regulations and guidance documents or action levels.

(b) Processing and production records showing adherence to scheduled processes, including records of pH measurements and other critical factors intended to ensure a safe product, shall be maintained and shall contain sufficient additional information such as product code, date, container size, and product, to permit a public health hazard evaluation of the processes applied to each lot, batch, or other portion of production.

(c) All departures from scheduled processes having a possible bearing on public health or the safety of the food shall be noted and the affected portion of the product identified; these departures shall be recorded and made the subject of a separate file (or log identifying the appropriate data) delineating them, the action taken to rectify them, and the disposition of the portion of the product involved.

(d) Records shall be maintained identifying initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use.

(e) Copies of all records provided for in paragraphs (b), (c), and (d) of this section shall be retained at the processing plant or other reasonably accessible location for a period of 3 years from the date of manufacture.

[44 FR 16235, Mar. 16, 1979, as amended at 65 FR 56479, Sept. 19, 2000]

PART 115—SHELL EGGS

AUTHORITY: 21 U.S.C. 342, 371; 42 U.S.C. 243, 264, 271.

§ 115.50 Refrigeration of shell eggs held for retail distribution.

(a) For purposes of this section a "retail establishment" is an operation that stores, prepares, packages, serves, vends, or otherwise provides food for human consumption directly to consumers.

(b) Except as provided in paragraph (c) of this section, all shell eggs, whether in intrastate or interstate commerce, held for retail distribution:

(1) Shall promptly be placed under refrigeration as specified in paragraph (b)(2) of this section upon receipt at a retail establishment, except that, when short delays are unavoidable, the eggs shall be placed under refrigeration, as soon as reasonably possible; and

(2) Shall be stored and displayed under refrigeration at an ambient temperature not greater than 7.2 °C (45 °F) while held at a retail establishment.

(c) Shell eggs that have been specifically processed to destroy all viable *Salmonella* shall be exempt from the requirements of paragraph (b) of this section.

(d) Under sections 311 and 361 of the Public Health Service Act (PHS Act), any State or locality that is willing and able to assist the agency in the enforcement of paragraph (b) of this section, and is authorized to inspect or regulate retail establishments, may, in its own jurisdiction, enforce paragraph (b) of this section through inspections under paragraph (f) of this section and through administrative enforcement remedies identified in paragraph (e) of this section until FDA notifies the State or locality in writing that such assistance is no longer needed. When providing assistance under paragraph (e) of this section, a State or locality may follow the hearing procedures set out in paragraphs (e)(2)(iii) through (e)(2)(iv) of this section, substituting, where necessary, appropriate State or local officials for designated FDA officials or may utilize State or local hearing procedures if such procedures satisfy due process.

(e) This section is established under authority of both the Federal Food, Drug, and Cosmetic Act (the act) and the PHS Act. Under the act, the agency can enforce the food adulteration provisions under 21 U.S.C. 331, 332, 333, and 334. However, 42 U.S.C. 264 provides for the issuance of implementing enforcement regulations; therefore, FDA has established the following administrative enforcement procedures for the diversion or destruction of shell eggs and for informal hearings under the PHS Act: